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October 13, 2016 - Original Filing Date  
October 20, 2016 - Redacted Filing Date

REDACTED - PUBLIC VERSION

The Honorable Leonard P. Stark  
United States District Court  
for the District of Delaware  
844 North King Street  
Wilmington, DE 19801

*VIA ELECTRONIC FILING*

Re: *Cosmo Technologies Ltd. v. Lupin Ltd. et al.*  
C.A. No. 15-669-LPS

Dear Chief Judge Stark:

Plaintiffs Cosmo Technologies Ltd. ("Cosmo"), Valeant Pharms. Int'l, and Valeant Pharms. Luxembourg S.à r.l. (collectively, "Plaintiffs") submit this letter in opposition to the October 12, 2016 letter (D.I. 80) from Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"). Plaintiffs respectfully request that the Court sustain their objection to Dr. Graham Buckton accessing Plaintiffs' confidential information under the Protective Order and disqualify him from serving as Lupin's expert consultant in this matter because he had a confidential relationship with Cosmo under which he received confidential information related to the issues in this litigation.

**The Technology at Issue and Dr. Buckton's Prior Relationship with Cosmo.** This is a Hatch-Waxman case concerning Lupin's attempt to market a generic version of Uceris, an extended-release budesonide tablet used to treat ulcerative colitis. Uceris employs the MMX<sup>®</sup> ("multimatrix") technology developed by Cosmo and described in the patents-in-suit. Ex. 1. The patents-in-suit are directed to, among other things, formulations containing multiple matrices (e.g., U.S. Patent No. RE 43,799, claim 1) and formulations containing macroscopically homogenous structures containing different types of excipients (e.g., U.S. Patent No. 9,320,716, claim 22). During the course of its development work, Cosmo discovered that inventive variations on the MMX platform could be applied to different active ingredients. One such application is a separately patented extended-release mesalamine formulation developed by Cosmo in partnership with Shire and now marketed in the United States as Lialda. Ex. 1.

[REDACTED]

[REDACTED]

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[REDACTED]

Despite consulting with Shire and Cosmo on the development of particular applications of MMX technology, Dr. Buckton agreed to consult with Lupin in litigation against Cosmo concerning that technology's application to budesonide. Thus, when Lupin disclosed Dr. Buckton as a proposed expert, Plaintiffs promptly and in good faith objected under the protective order.

**Disqualification is Necessary Because Dr. Buckton Received Confidential Information Relevant to the Litigation as Part of a Confidential Relationship with Cosmo.** Disqualification is appropriate when (1) it was objectively reasonable for the party seeking disqualification to have concluded that a confidential relationship existed with the expert; and (2) confidential or privileged information was actually disclosed to the expert. *E.g., Merck Sharp & Dohme Corp. v. Teva Pharms. USA, Inc.*, 2015 WL 5163035, at \*2 (D. Del. 2015). Courts also consider "the public interest in allowing or not allowing an expert to testify." *Id.* Under this standard, Dr. Buckton should be disqualified.

"The 'objectively reasonable belief' standard is not a high hurdle to clear," and the facts here establish that such a confidential relationship existed. *See, e.g., AstraZeneca Pharms. LP v. Teva Pharms. USA, Inc.*, 2007 WL 4292384, at \*2 (D.N.J. 2007).

[REDACTED]

[REDACTED] In such a situation, Cosmo would have the objectively reasonable belief that it had a confidential relationship with Dr. Buckton and PharMaterials. *See* Ex. 4, ¶ 6.

Further, the documentary evidence establishes that confidential Cosmo information was disclosed to Dr. Buckton.

[REDACTED]

Moreover, the confidential information received by Dr. Buckton is relevant to this litigation. The asserted '799 patent, for example, requires three matrices in which other matrices or ingredients are dispersed. Likewise, claim 22 of the '716 patent requires a macroscopically

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homogenous structure containing lipophilic, amphiphilic, and hydrophilic excipients, which controls drug release. [REDACTED]

[REDACTED] Because Dr. Buckton received confidential information relevant to this litigation from Cosmo in the context of a confidential relationship, he should be disqualified. *See, e.g., Auto-Kaps, LLC v. Clorox Co.*, 2016 WL 1122037, at \*3-4 (E.D.N.Y. 2016) (excluding expert who had previously consulted with objecting party on the technology at issue); *WesternGeco LLC v. Ion Geophysical Corp.*, 2010 WL 2266610, at \*2 (S.D. Tex. 2010) (excluding expert who received confidential information "that could, and probably would, be relevant to this litigation"); *Medeva Pharma Suisse AG v. Roxane Labs., Inc.*, 2008 WL 5500965, at \*2 (D.N.J. 2008) (excluding gastroenterologist who discussed confidential information concerning research and development with moving party); *AstraZeneca Pharms.*, 2007 WL 4292384, at \*2-4 (excluding doctor who was "exposed to" confidential "marketing, business, and clinical information"); *In re Incretin Mimetics Prods. Liab. Litig.*, 2015 WL 1499167, at \*5-8 (S.D. Cal. 2015) (excluding expert who had access to confidential technical information and "mental impressions from interactions" with moving party).<sup>1</sup>

The policy objectives favoring disqualification – "ensuring fairness and preventing conflicts of interest" – also support Plaintiffs' position. *E.g., Oracle Corp. v. DrugLogic, Inc.*, 2012 WL 2244305, at \*5 (N.D. Cal. 2012). It is fundamentally unfair to allow [REDACTED]

[REDACTED] and then turn around and offer his services to an adverse party seeking to attack another application of that technology in litigation. By contrast, the policy considerations counseling against disqualification – "maintaining accessibility to experts" and "encouraging experts to pursue their professions" – are inapplicable here. *E.g., Medeva Pharma*, 2008 WL 5500965, at \*3. Lupin has not and cannot contend that there are not other experts available to consult on issues related to extended-release formulations targeting the gastro-intestinal tract. Moreover, as evidenced by his *curriculum vitae* (Ex. 5 at PDF pp. 3, 43-45), Dr. Buckton has an active consulting practice covering patent litigation expert services and other areas that will be unaffected by Plaintiffs' request for disqualification, which is limited to the particular facts here. For at least these reasons, Plaintiffs' respectfully request that the Court sustain its objection to Dr. Buckton and disqualify him from serving as Lupin's expert in this matter.

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<sup>1</sup> Neither *Audio MPEG* nor *Cellular Commcn's* (Exhibits G-H to Lupin's letter) justify concluding that the confidential information at issue here does not warrant disqualification because in *Audio MPEG* the previously disclosed information did not have a substantial relationship to the instant litigation (Ex. G at 10) and in *Cellular Commcn's* there was no confidential information disclosed (Ex. H at 6-7). Likewise, courts have recognized that disclosure of non-litigation based confidential technical information may justify disqualification. *See, e.g., Pellerin v. Honeywell Int'l Inc.*, 2012 WL 112539, at \*2-3 & n.1 (S.D. Cal. 2012).

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Respectfully,

*/s/ Maryellen Noreika*

Maryellen Noreika (#3208)

MN/dlw

cc: Clerk of Court (Via Hand Delivery)  
All Counsel of Record (Via Electronic Mail)